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Comments on Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs, 69 FR 19673 (April 13, 2004)

Dear Dr. Vogl:

We appreciate the opportunity to comment on the proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs, and we applaud the efforts by the Department of Health and Human Services' (HHS) Substance Abuse and Mental Health Services Administration (SAMHSA) to expand the program. We understand that HHS is making these proposed revisions to fulfill a mandate to utilize the "best available technology" for drug-free programs. We wish to comment specifically on three recommendations in the proposed regulations addressing oral fluid testing.

1. Proposal for the collection of oral fluid as a "neat" specimen

In section 2.5(b), the collection of oral fluid is specified as "2mL collected as a 'neat specimen' (divided as follows: at least 1.5mL for the primary specimen and at least 0.5mL for the split specimen)." Based on our experience as a third party provider of drug and alcohol testing, we believe that collection of oral fluid using an approved Food and Drug Administration (FDA) collection device is also an acceptable if not preferred collection method.

Spitting into a tube to obtain a "neat" specimen does not necessarily represent the "best available technology," nor do we believe this collection method would be practical. Our customers appreciate the dignity of oral fluid collection but we do not believe that dignity continues to exist for donors required to spit into a container. The additional cost and time required for collecting "neat" specimens could be significant. The collection environment would require control and possibly sanitizing, and the allowance of 15 minutes to provide a specimen is five times longer than the collection process with the FDA-approved oral specimen collection device. Finally, specimen collection of oral fluid by an absorbent pad has been shown to be relatively consistent, and the donor is not able to control any variances by attempting to dilute or adulterate the sample.

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2. Proposal for collecting a urine specimen with each oral fluid specimen.

Under section 2.3(a) and section 8.3(a)(16) that addresses the specific collection procedures for an oral fluid specimen, it is specified that a urine specimen shall be collected, for the purpose of addressing the possibility of a positive oral fluid test result from passive exposure to cannabis smoke. We believe this additional specimen collection is unnecessary and adds unjustified burden and cost for employers. Scientific data demonstrates that positive oral fluid test results from any realistic exposure situation would be extremely unlikely.

For example, since these proposed guidelines were drafted, authoritative scientific data on the effect of environmental exposure to cannabis smoke on oral fluid tests has been developed and accepted by the Journal of Analytical Toxicology for publication (Dr. Edward Cone et al.). Specifically, this research demonstrates that environmental contamination is limited to only extreme exposure conditions (several joints smoked in a small, sealed room), and then for only short periods after exposure (up to 30 minutes). The likelihood of environmentally caused positive test results is extremely low if not negligible and is not worth the cost to the employers? -

3. Applicability of oral fluids testing to return-to-duty, follow-up testing.

In section 2.2, oral fluid is specified for “**pre-employment, random, reasonable suspicion/cause and post-accident testing.**” Although it is stated that the basis for this change is due to the claimed short detection time for drugs in oral fluids, a review of published data demonstrates that oral fluid has sensitivities comparable to urine for detection of drug use in the workplace.

We believe oral fluid testing is appropriate for all testing scenarios. It is clearly suited for Return-to-Duty and Follow-Up testing, because it detects recent drug use. A worker successfully completing a substance abuse recovery program and refraining from drugs will quickly test negative for drugs sooner with oral fluid testing compared to other testing methods

Oral fluid testing is also uniquely able to detect illicit drug use. A worker trying to cheat on a substance abuse program is very likely to attempt to tamper with urine specimens by diluting or adulterating them, or by substituting clean urine. Oral fluid testing provides a directly observed collection that virtually eliminates the opportunity to tamper with specimens.

We again thank the Department for this opportunity to provide information to assist it in drafting and finalizing drug-testing guidelines and for their careful consideration of these points. We are eager to offer any additional information that will assist SAMHSA in fulfilling its statutory obligations. If you have any questions please do not hesitate to contact Stan Linnertz at 1-800-288-8504 x3218 or Dan Shoemaker at 703-838-7995

Sincerely,



Jim Collins
President